HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Refer to: CFN 1121769

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

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January 6, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. H. Wayne Sale
President and Chief Executive Officer
Health First
2205 Perl Road
Richmond, Virginia 23230

Dear Mr. Sale:

The Food and Drug Administration (FDA) conducted an inspection of your liquid Oxygen, USP, manufacturing facility on December 8-9, 1998.

That inspection found significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals (CGMP) regulations (Title 21, Code of Federal Regulations (CFR), Part 211). These deviations cause your liquid Oxygen, USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for, manufacturing, processing, packing, or holding are not in conformance with CGMP regulations.

The deviations included the following:

- Failure to test each component and the final product for conformity with all appropriate specifications for purity, strength, and quality, or to have adequate reports of analysis from the suppliers of the components.

- Failure to establish written procedures describing such operations as a quality control unit, testing and inspection procedures, distribution, training, labeling, complaint handling, and recalls.

- Failure to inspect home cryogenic vessels before filling.

- Failure to prepare batch production and control records.

At the conclusion of the inspection, you were given a written list of inspectional observations (FDA-483) which was discussed with you. We acknowledge that you responded to the FDA-483 in a letter dated December 16, 1998. We have reviewed your response; however, it does not adequately address each of the CGMP deficiencies noted during our inspection. We further note that you are recalling the liquid oxygen and that you informed our investigator on December 29, 1998, that your firm would cease the production of liquid oxygen effective January 1, 1999.

Please notify us should you decide to resume manufacturing operations. The corrective actions you have taken and/or promised will be verified on the next scheduled inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your facility. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,

Carl E. Draper
Acting Director, Baltimore District

cc: Virginia Board of Pharmacy
6606 West Broad Street
Richmond, Virginia 23230-1717